Message

From: Goodis, Michael [Goodis.Michael@epa.gov]
Sent: 12/15/2021 1:49:08 PM
To: Messina, Edward [Messina.Edward@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Dinkins, Darlene [Dinkins.Darlene@epa.gov]
CC: Chandrasekaran, Devi [Chandrasekaran.Devi@epa.gov]; Aranda, Amber [aranda.amber@epa.gov]; Pittman, Forrest [Pittman.Forrest@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Overbey, Dian [Overbey.Dian@epa.gov]; Teter, Royan [Teter.Royan@epa.gov]; Lara, Rhina [Lara.Rhina@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]
Subject: RE: Slides for Prop 65 AA briefing - tomorrow, or push?
Attachments: FYI: SCOTUS Invitation to SG to File Brief Expressing Views (FIFRA Preemption; Monsanto v. Hardeman)

Sharing the attached with the Prop 65 team for awareness.
This is a new development to consider which was brought to the US Supreme Court – OGC may have more to add.

Monsanto Company respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

INTRODUCTION

Monsanto manufactures Roundup, the world's most widely used herbicide. Roundup's active ingredient is glyphosate. Like any herbicide, glyphosate is subject to extensive regulatory scrutiny by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's scrutiny includes reviewing whether glyphosate poses risks to humans and ensuring any risks are communicated to the public.

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For decades, EPA has studied the enormous body of science on glyphosate and repeatedly concluded that glyphosate does not cause cancer in humans. As EPA explained below, it has approved 44 versions of Roundup labeling since 1991—all without a cancer warning. And in 2019 it instructed glyphosate manufacturers that no request to add a cancer warning would be approved because that warning would be false and misleading. Despite EPA's repeated findings—confirmed by national regulators around the world, including in Australia, the E.U., Canada, and New Zealand—a working group at the International Agency for Research on Cancer (IARC) classified glyphosate in 2015 as "probably carcinogenic to humans." EPA and other regulators reviewed and rejected IARC's conclusion, which did not identify either the circumstances under which glyphosate might cause cancer or the amount of exposure required. Still, based on that slender reed, many thousands of litigants (including respondent Edwin

Hardeman) sued Monsanto asserting that it failed to warn them about the cancer risks of using Roundup. The Ninth Circuit's decision here—affirming a $25 million damages award—merits review because it conflicts with this Court's and other circuits' decisions on two important federal questions. *See* S. Ct. R. 10(a), (c).

First, the Ninth Circuit held that FIFRA did not preempt respondent's state-law failure-to-warn claim despite EPA's conclusion that such a cancer warning would be false and therefore prohibited by FIFRA. That contravenes this Court's holding that any state labeling requirement not "*genuinely* equivalent" to a FIFRA labeling requirement is preempted. *Bates* v.

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Dow Agrosciences LLC, 544 U.S. 431, 454 (2005). The ruling below also splits with how this Court and others have understood a nearly identical preemption provision in another federal statute.

Second, the Ninth Circuit affirmed the admission of expert opinions that glyphosate can cause non-Hodgkin's lymphoma and caused respondent's cancer specifically, even though those opinions rested on little more than subjective intuitions. That conflicts with *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), which requires trial courts to play "a gatekeeping role" to ensure that expert opinions are reliable, and with Federal Rule of Evidence 702, which requires expert opinions to be the product of "reliable principles and methods," "reliably applied … to the facts of the case," Fed. R. Evid. 702(c)-(d). The admissibility ruling also departs from other circuits' precedent, which would have likely rejected the testimony at issue.

These deviations merit review, particularly because this case is a "bellwether trial for the [Roundup] cases consolidated in a multidistrict litigation," App.2a—meaning that the decision below will control thousands of other federal suits, and undoubtedly influence still others pending across the country. Together, the Ninth Circuit's errors mean that a company can be severely punished for marketing a product without a cancer warning when the near-universal scientific and regulatory consensus is that the product does not cause cancer, and the responsible federal agency has forbidden such a warning. That is not, and should not be, the law.

Michael L. Goodis, P.E.
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From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Monday, December 06, 2021 3:32 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
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Subject: RE: Slides for Prop 65 AA briefing - tomorrow, or push?

Push. Because I would like to hear from the team first.

Thanks,
Ed

Ed Messina, Esq.
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From: Aubee, Catherine <Aubee.Catherine@epa.gov>
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Internal, deliberative

Hello Ed, all,

We are on the calendar for an AA briefing on Prop 65 tomorrow: **Tuesday, 12/7, at 4pm**. Thanks to all who have contributed to the slides.

Ex. 5 Deliberative Process (DP)

Best,
Catherine
Associate Director
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